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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/517,940

Applicant(s)

GLOBERMAN, OREN

Examiner

JONATHAN A. HOLLM

Art Unit

3734

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 and 58-77 is/are pending in the application.
- 4a) Of the above claim(s) 7-10, 20, 31-33 and 65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-19, 21-30, 34-43, 58-64 and 66-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 02/12/2010
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The Amendment filed 31 December 2009 has been entered. **Claims 1-43 and 58-77** are pending in the application with **claims 7-10, 20, 31-33, and 65** (see below regarding claim 8) being withdrawn from further consideration and **claims 44-57** being cancelled. The previous objections to the claims and rejections of **claims 3, 8-9, and 30-37** under 35 U.S.C. 112, second paragraph are withdrawn in light of Applicant's amendments to the claims. Response to applicant's arguments can be found at the end of this office action.

Election/Restrictions

2. Amended **claim 8** is directed to an invention of a non-elected sub-species (sub-species A-2), since the subject matter of withdrawn claim 7 that reads on sub-species A-2 has been added in the amendment to claim 8. Accordingly, **claim 8** is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b).

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 12 February 2010 was filed after the mailing date of the Non-final Office Action on 31 August 2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore the limitations:

only one of the at least two extensions comprising a plurality of hinges (claims 7-8); and

the extensions extending axially away or axially towards the body prior to moving apart of the anchor points (claims 20-21);

the at least two hinges being bendable elements with no specific bending points defined thereon (claim 75)

must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. **Claims 1, 3, 12, 17-19, and 32** are objected to because of the following informalities:

In **claim 1**, the phrase "defined on one of said at least two elongate extensions" (lines 7-8) should read - - defined on said at least one of said at least two elongate extensions - - .

In **claim 3**, the phrase "elongate extension are a mirror of the hinges" (line 2) should read - - elongate extension mirror the hinges - - .

In **claim 12**, the phrase "bend at least one of said extensions at least two points" (line 2) should read - - bend at least one of said extensions at at least two points - - .

In **claims 17-19**, the phrase "said extension" (line 2) should read - - said at least one of said at least two extensions - - .

In **claim 32**, the phrase "flared section provides has a flaring axis" (line 2) should read - - flared section has a flaring axis - - .

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. **Claims 1-6, 11-19, 21-30, 34-38, 58-60, 64, and 75-77** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
8. **Claim 1** recites the limitation "the two anchor points" in line 3. It is unclear which two anchor points are being referred to since the claim requires a least two anchor points, in which there may be more than two anchor points. **Claims 2-6, 11-19, 21-31, 34-38, 58-60, 64, and 75-77** are rejected as being dependent upon rejected claim 1.
9. **Claim 26** recites the limitation "said plurality of hinges" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.
10. **Claim 38** recites the limitation "said flared section" in line 1. There is insufficient antecedent basis for this limitation in the claim.
11. **Claim 60** recites the limitation "said stent body" in line 1. There is insufficient antecedent basis for this limitation in the claim.
12. **Claim 75** recites the limitation "defined on it". It is unclear as to what "it" refers to, rendering the claim indefinite.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

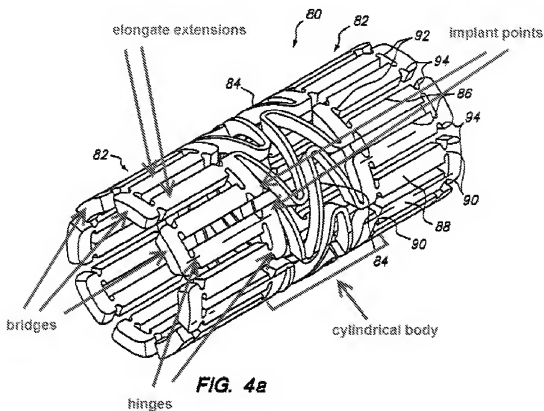
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. **Claims 1-3, 5-6, 17-18, 21-25, 27-29, 58, 60, 64, and 75-77** are rejected under 35 U.S.C. 102(a or e) as being anticipated by Shanley (US Patent Number 6,293,967).

Shanley discloses a stent including a cylindrical body defining at least two implant points that move relative to each other, at least two elongate extensions, a bridge coupling at least two of said elongate extensions, and at least two hinges defined on at least one of said extensions at least two of which have different preferred bending directions (see annotated figure 4a below); each of the extensions including a plurality of hinges; the hinges of one extension being a mirror of hinges on another, coupled extension; at least one of the plurality of hinges having a bending direction different from a corresponding hinge on a second, coupled extension; at least one of the hinges having a resistance to bending different from a corresponding hinge on a second extension (column 7, line 45 – column 8, line 65); at least one of the hinges including a cut/weaker portions in a position along an extension (column 9, lines 50-59); the extensions being capable of extending axially away from the body, prior to moving apart the implant points; the bridge being defined at an end of the extensions, deformable, and being more resistant to bending than the hinges; the hinges being plastically deformable (column 4, lines 43-47); the implant being adapted for implanting in a blood vessel; the elongate extensions facing each other across an aperture in the stent; the body being adapted to deform such that parts of the extensions deform and other parts

do not deform; the hinges being parts of struts of the stent; the hinges being bendable elements with no specific bend points (see figure 3D); and the hinges being plastically deformable portions defined in the extensions.



Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. **Claims 4 and 26** is rejected under 35 U.S.C. 103(a) as being unpatentable over Shanley (US Patent Number 6,293,967).

Regarding **claim 4**, the device of Shanley is not explicitly disclosed with the plurality of hinges on one extension having different axial locations than corresponding hinges on a second, coupled extension. However, Shanley teaches that the positions of the hinges may be altered to better suit a stent design (column 8, line 66 – column 9, line 13). It would have been obvious to one having ordinary skill in the art at the time the invention was made modify the device of Shanley to have the hinges on one extension have different axial locations than corresponding hinges on a second, coupled extension, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Regarding **claim 26**, the device of Shanley discloses the claimed invention except for the number of hinges being within a specific range. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Shanley to include the specified number of hinges, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

17. **Claim 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over Shanley (US Patent Number 6,293,967) in view of Vargas et al (US Patent Number 6,428,550).

The device of Shanley discloses the claimed invention except that the hinges include cuts or weakenings instead of a bore. Vargas et al shows that a hinge including a bore is an equivalent structure known in the art (see figure 13; column 8, lines 10-21). Therefore, because these two hinge configurations were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute a hinge including a bore for a hinge including a cut or weakening.

18. Claims 1-6, 11-19, 21-30, 34-38, 58-60, 64, 66-69, 71-72, and 74-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi et al (US Patent Number 6,325,826) in view of Shanley (US Patent Number 6,293,967) and Vargas et al (US Patent Number 6,428,550).

Vardi et al discloses a stent including a cylindrical body sized and shaped to be implanted in a vascular bifurcation and defining at least two implant points that move relative to each other, an aperture defined in a side of the expandable cylindrical body and designed for allowing passage to a side branch, at least two elongate extensions adjacent the aperture and configured to be extended away from the body into a side vessel, and a bridge coupling at least two of the extensions (see annotated figure 10 below); the extensions being capable of extending axially toward the body prior to expansion of the body; the bridge being defined at an end of the extensions and deformable; the extensions defining a flared section of the stent; the flared section being defined on a side of the stent; the flared section capable of having an axis generally perpendicular to an axis of the stent; the flared section being generally cylindrical; the

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stent and flared section being mesh; and the extensions facing each other across the aperture.

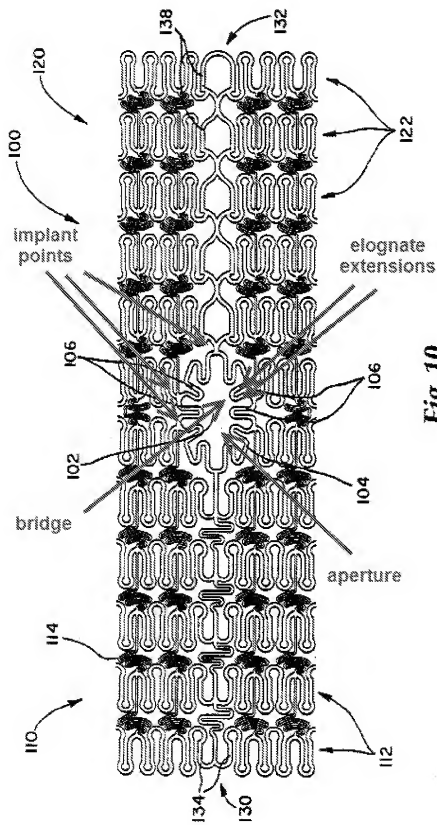


Fig. 10

The device of Vardi et al is not explicitly disclosed with at least two hinges defined on at least one of said extensions at least two of which have different preferred bending directions. Shanley teaches providing at least two hinges on an extension having different bending directions (see fig 3e). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Vardi et al to include at least two hinges defined on at least one of the extensions, as taught by Shanley, since Shanley teaches that such a configuration allows for more controlled expansion characteristics of the elongate members (column 6, lines 29-54).

The modified device of Vardi et al in view of Shanley is not explicitly disclosed with the hinges being defined on at least one of the extensions to allow a flaring of the at least one extension as an outcome of deformation of the body. Vardi et al teach the extensions being flared out by a balloon (see figure 13f). Vargas et al teach configuring hinges on elongate extensions to allow for flaring of the at least one extension as an outcome of deforming a cylindrical body (i.e., without the use of a balloon to cause the flaring; see figures 3-4; column 4, line 54 - column 5 line 19). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Vardi et al in view of Shanley to configure the hinges to allow for a flaring of at least one extension upon deformation of the body, in view of Vargas et al, in order to simplify delivery of device by obviating the need for a balloon to flare the extension in a branch vessel.

Regarding **claims 2-3 and 5-6**, Shanley teaches each of the extensions including a plurality of hinges; the hinges of one extension being a mirror of hinges on another,

coupled extension; at least one of the plurality of hinges having a bending direction different from a corresponding hinge on a second, coupled extension (see figure 4a); and at least one of the hinges having a resistance to bending different from a corresponding hinge on a second extension (column 7, line 45 – column 8, line 65);.

Regarding **claim 4**, the modified device of Vardi et al in view of Shanley and Vargas et al is not explicitly disclosed with the plurality of hinges on one extension having different axial locations than corresponding hinges on a second, coupled extension. However, Shanley teaches that the positions of the hinges may be altered to better suit a stent design (column 8, line 66 – column 9, line 13). It would have been obvious to one having ordinary skill in the art at the time the invention was made modify the device of Vardi et al in view of Shanley and Vargas et al to have the hinges on one extension have different axial locations than corresponding hinges on a second, coupled extension, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Regarding **claims 11-12**, the hinges of the modified device of Vardi et al in view of Shanley and Vargas et al cooperate with the bridge to bend the extensions in a direction with a component perpendicular to a device plane of the body at least two points in different direction.

Regarding **claims 13-16**, the modified device of Vardi et al in view of Shanley and Vargas et al discloses the claimed invention except for the hinges being arranged to bend the extensions to a specific range of angles. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of

Vardi et al in view of Shanley and Vargas et al to have the hinges arranged to bend the extensions to an angle within the specified range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding **claims 17-19 and 76**, Vargas et al teach hinges being formed of cuts, weakenings, and bores (see figure 13; column 8, lines 10-21).

Regarding **claims 24-25 and 77**, Shanley teaches being more resistant to bending than the hinges and the hinges being plastically deformable (column 4, lines 43-47).

Regarding **claim 26**, the modified device of Vardi et al in view of Shanley and Vargas et al discloses the claimed invention except for the number of hinges being within a specific range. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Vardi et al in view of Shanley and Vargas et al to have the specified number of hinges, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding **claim 60**, Shanley teaches the stent being structured such that parts of the extensions deform and parts do not deform (column 4, lines 37-52).

Regarding **claim 64**, Shanley and Vargas et al teach the hinges being parts of struts of the stent.

Regarding **claim 75**, Shanley teaches the hinges being bendable elements with no specific bending points defined on them (see figure 3D).

19. **Claim70** is rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi et al (US Patent Number 6,325,826) in view of Shanley (US Patent Number 6,293,967) and Vargas et al (US Patent Number 6,428,550), as applied to claim 66 above, and further in view of Globerman et al (US Patent Number 6,402,777).

The device of Vardi et al in view of Shanley and Vargas et al is not explicitly disclosed with at least one of the extensions including a radio-opaque marker that extends away from the body with the extension. Globerman et al teach a stent with a radio-opaque marker attached to and capable of moving with an extension during expansion of a stent (see figures 1, 2, and 8-9). It would have been obvious for a person having ordinary skill in the art at the time of the invention to modify the device of Vardi et al in view of Shanley and Vargas et al to have at least one of the extensions include a radio-opaque marker that extends away from the body with the extension in view of Globerman et al, since Globerman et al teach that such a configuration allows a stent to be viewed during a procedure in order to assure proper placement of the stent (column 2, lines 15-23).

20. **Claims 39-43 and 61-63** are rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi et al (US Patent Number 6,325,826) in view of Vargas et al (US Patent Number 6,428,550).

Vardi et al teach a method of distorting a cylindrical stent structure having at least two extensions coupled at a point thereof and sized and shaped to be placed in a vascular bifurcation including changing the relative position of two points on said extensions (the implant points (see annotated figure 10 above) are moved relative to each other during inflation of the delivery balloon) that are distanced from the coupling point (see figures 13a-d), but is disclosed with using a balloon to bend the extension instead of transforming, using a plurality of pre-defined hinges, tension forces applied by said changing into forces that bend said structure in a plane outside of a plane defined by said changing. Vardi et al teach transforming, using a plurality of pre-defined hinges, tension forces applied by changing the relative position of points on extensions coupled to each other into forces that bend the extensions outside of a plane defined by the changing (i.e., without the use of a balloon; see figures 3-4; column 4, line 53 – column 5, line 9). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the method of Vardi et al to transform, via a plurality of hinges, tension forces applied by said changing into forces to bend said extensions in a plane outside of a plane defined by the changing, in view of Vargas et al, in order to simplify delivery of device by obviating the need for a balloon to flare the extension in a branch vessel.

Regarding **claim 41**, Vardi et al teach the changing being applied by radially expanding the cylindrical stent structure.

Regarding **claims 42-43**, Vardi et al disclose transforming comprising flaring out extensions including a change in angle to more than 50 degrees relative to an axis of the cylinder (see figure 13f).

Regarding **claim 61**, Vardi et al discloses two extensions facing each other.

Regarding **claim 62**, Vardi et al disclose the extensions being extended into a side branch of a vessel bifurcation.

Regarding **claim 63**, Vargas et al disclose the transforming comprising deforming parts of the extensions and not deforming other parts of the extensions.

21. **Claim73** is rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi et al (US Patent Number 6,325,826) in view of Vargas et al (US Patent Number 6,428,550).

Vardi et al disclose a method of deploying a stent including guiding an expandable cylindrical body to a vessel bifurcation, expanding the expandable cylindrical body, and extending away at least two extensions of the expandable body (see figures 13a-f). The method of Vardi et al teaches extending the at least two extensions by inflating a balloon instead of by expanding the body. Vargas et al teach extending extensions away from a cylindrical body by expanding a cylindrical body (i.e., without the use of a balloon to cause the extending; see figures 3-4; column 4, line 53 – column 5, line 19). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the method of Vardi et al to have the extending occur via expanding the body, in view of Vargas et al, in order to simplify the delivery of

the stent by obviating the need for a balloon to extend the extensions into a branch vessel.

Response to Arguments

22. Applicant's arguments with respect to **claims 1-6, 11-19, 21-30, 34-43, 58-64, and 66-77** have been considered but are moot in view of the new ground(s) of rejection.

23. Regarding Applicant's arguments concerning the objections to the drawings:

Figures 8B, 8d, and 8F referenced by the Applicant do not show the claimed limitation of "only one of the two extensions includes a plurality of hinges," as alleged by Applicant. These figures are merely side views of figures 8A, 8C, and 8E (respectively) which illustrate two extensions including a plurality of hinges.

Figures 9A-9C referenced by the Applicant do not show the claimed limitation of "extensions extending axially away from the body prior to moving apart of the anchor points," as alleged by Applicant. These figures are merely illustrations of different flared sections on a stent body. No mention in the description of these figures mentions any elongate members extending away from the body prior to moving apart of any anchor points. Further, descriptions of these figures discuss extensions assuming these configurations via hinges, which are disclosed throughout the specification as acting under the influence of moving anchor points.

Figure 9F referenced by the Applicant does not show the claimed limitation of "extensions extending axially toward the body prior to moving apart of the anchor points," as alleged by Applicant. This figure merely illustrates a flared section on a side

of a stent body. No mention in the description of this figure mentions any elongate members extending toward the body prior to moving apart of any anchor points.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN A. HOLLM whose telephone number is (571) 270-7529. The examiner can normally be reached on Monday - Friday 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.AH./

/TODD E. MANAHAN/

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Supervisory Patent Examiner, Art Unit 3734